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MARSHALL, DENNEHEY, WARNER, COLEMAN & GOGGIN
425 EAGLE ROCK AVENUE, SUITE 302
ROSELAND, NJ 07068
(973) 618-4100
ATTORNEYS FOR DEFENDANTS-
New York University School of Medicine and New York University Hospitals Center

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

CHAYA GROSSBAUM and MENACHEM GROSSBAUM, her spouse, individually and as guardians ad litem of the infant, ROSIE GROSSBAUM, Plaintiffs, v. GENESIS GENETICS INSTITUTE, LLC of the State of Michigan, MARK R. HUGHES, NEW YORK UNIVERSITY SCHOOL OF MEDICINE and NEW YORK UNIVERSITY HOSPITALS CENTER, both corporations in the State of New York, ABC CORPS. 1-10, and JOHN DOES 1-10, Defendants.	Hon. Garrett E. Brown, Jr. Civil Action No. 07-1359 (GEB) **BRIEF IN SUPPORT OF THE MOTION OF DEFENDANTS NEW YORK UNIVERSITY SCHOOL OF MEDICINE AND NEW YORK UNIVERSITY HOSPITALS CENTER FOR SUMMARY JUDGMENT AND FOR FINALITY OF JUDGMENT**

BRIEF IN SUPPORT OF THE MOTION OF DEFENDANTS NEW YORK UNIVERSITY SCHOOL OF MEDICINE AND NEW YORK UNIVERSITY HOSPITALS CENTER FOR SUMMARY JUDGMENT AND FOR FINALITY OF JUDGMENT

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I. INTRODUCTION

Defendants New York University School of Medicine and New York University Hospitals Center (collectively referred to as "the NYU defendants") respectfully ask this Court to enter an Order granting summary judgment in their favor pursuant to Federal Rule of Civil Procedure 56 and making that judgment final pursuant to Federal Rule of Civil Procedure 54(b).

F.R.Civ.P. 56(b) permits defending parties to move for summary judgment, "with or without affidavits," and F.R.Civ.P. 56(c) provides that summary judgment "shall be rendered forthwith if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law."

In this case, there is no genuine issue of material fact, and the NYU defendants are entitled to judgment in their favor as matter of law, because plaintiffs cannot establish their liability claim against the NYU defendants for several reasons.

Additionally, when the case presents more than one claim for relief or involves more than one party, F.R.Civ.P. 54(b) permits the Court to enter a final judgment as to fewer than all claims or parties by expressly determining that there is no just reason for delay. In this case, the Court's grant of summary judgment in favor of the NYU defendants should be made final, because there is no just reason to delay the finality of that judgment pending the resolution of plaintiffs' claims against Genesis, since those claims are distinct and can be separated from the claims against the NYU defendants, and since the NYU defendants are presently entitled to the entry of judgment in their favor.

II. STATEMENT OF THE CASE

Viewed in the light most favorable to the plaintiffs, as a motion for summary judgment is obliged to do, the record in this case produces the following facts.

A. OVERVIEW OF THE CASE AND OF THE IVF/PGD PROCESS

Plaintiffs Chaya and Menachem Grossbaum, individually and as guardians *ad litem* of their minor daughter Rosie,[1] commenced this civil negligence action against Genesis Genetics Institute, LLC ("Genesis"), its founder and director Mark R. Hughes ("Dr. Hughes") (collectively "Genesis" or "Dr. Hughes"), and the NYU defendants to recover damages in connection with the birth and raising of Rosie as a child affected by cystic fibrosis ("CF"). (Exhibit A, Complaint.)

Because plaintiffs knew that they were both unaffected genetic CF carriers and faced an inherent 25% chance of giving birth to a CF-affected child, plaintiffs sought the advice and counsel of rabbis in their religious sect on what options they had regarding their desire to have a child. (Exhibit B, Deposition of Chaya Grossbaum, p. 15-19, 30-31, 37-47, 49-50, 64-66; Exhibit C, Deposition of Chaya Grossbaum, p. 11-13, 14-15, 20.) The suggested course was to pursue a process of *in vitro* fertilization ("IVF") and preimplantation genetic diagnosis ("PGD"), and the recommendation was to see the NYU defendants' Frederick Licciardi, M.D. at the NYU IVF Center. (Exhibit B, p. 49-50, 64-65; Exhibit C, p. 12, 15, 20.)

The IVF aspects of the process were performed by Dr. Licciardi's group. The PGD aspects of the process were performed by Genesis and Dr. Hughes.

The initial IVF steps involved: obtaining blood samples from the plaintiffs and sending those samples to Genetics for the development of PGD test protocols specific to the plaintiffs' respective CF genes; inducing the development of, and obtaining several eggs from Mrs. Grossbaum; fertilizing the eggs with sperm from Mr. Grossbaum; developing embryos from the

[1] Plaintiffs' counsel has consented to the inclusion of Rosie's name and information concerning her birth in these papers and supporting Exhibits, as the information is germane to the case and was included in plaintiffs' complaint.

fertilized eggs over the course of two to three days; extracting a single cell from each of 10 PGD test-candidate embryos; sending the appropriately identified and packaged cells to Dr. Hughes at Genesis for PGD testing and analysis to determine the genetic suitability of the embryos for implantation to induce a pregnancy, along with controls and 10 media blanks for testing and analysis as a precaution against contamination of the cells' DNA; and, appropriately storing the candidate embryos for further development, pending receipt of a report on the PGD test results from Dr. Hughes.

The PGD steps conducted by Genesis and Dr. Hughes involved: the testing of the plaintiffs' blood samples to determine which CF genes they carried; developing and conducting appropriate PGD tests designed to detect the presence or the absence of the genes in the embryonic cells sent by NYU, and to determine whether or not the cells' DNA had become contaminated; and submitting a written report to NYU regarding the test results and genetic evaluation or "call" for each of the cells, and regarding the tests results of the controls and blanks.

Based upon the PGD evaluation report's calls regarding the cells' respective genetic suitability; based upon the report's indication of success with the controls and blanks; and based upon the report's indication that there was no evidence of DNA contamination, the IVF process resumed with a medical evaluation of the growth of the candidate embryos that had remained to determine their embryological viability for implantation to induce a pregnancy; a consultation with the plaintiffs concerning the results of the genetic PGD tests and of the embryological evaluation of the two best-suited embryos; a decision by the plaintiffs to proceed with the implantation of the embryos; the implantation of the embryos; and monitoring the resulting pregnancy for several weeks.

Plaintiffs do not claim any failure on the part of Dr. Licciardi and the NYU defendants regarding the information provided about, or the performance of, the IVF procedures involved in this case other than with the interpretation of Dr. Hughes' report regarding the genetic suitability of the cell from embryo #7 and the selection of that embryo in lieu of embryo #10, which had not developed enough embryologically to be viable for implantation.

The focus of plaintiffs' case with respect to Genesis and Dr. Hughes is on their method of PGD testing and genetic analysis without the use of "markers" to enhance detection of the genetic testing phenomenon known as allele drop-out ("ADO"); on the allegedly understated risk information that Dr. Hughes conveyed to plaintiffs about the chances of his PGD tests causing them to have a CF-infected child; and on the accuracy of the PGD report, which allegedly conveyed misdiagnosed information to Dr. Licciardi.

B. THE BASIS OF THE PLAINTIFFS' DECISION TO PROCEED WITH THE IVF/PGD PROCESS

In connection with the plaintiffs' decision to proceed with the IVF/PGD process, Dr. Licciardi and his staff informed the plaintiffs about all pertinent details of the IVF aspects of the process, and some aspects of the PGD process, specifically deferring to Dr. Hughes to provide the complete details of, and to answer all of the questions that the plaintiffs might have, about PGD. (Exhibit B, p. 56-61, 84-88; Exhibit C, p. 21-25.) Dr. Licciardi recognized that his specialty was in the practice of IVF and that Dr. Hughes was the PGD specialist. (Exhibit D, Deposition of Frederick Licciardi, M.D., p. 9, 61, 63-64.) Plaintiffs understood and accepted this division of specialties and expertise. (Exhibit B, p. 59-60.)

Dr. Hughes recognized that IVF practitioners such as Dr. Licciardi were experts in their field, but not experts in genetics and PGD as he was. (Exhibit E, 2/19/09 Deposition of Mark Hughes, M.D., Ph.D., p. 21-22; Exhibit F, 5/14/10 Deposition of Mark Hughes, M.D., Ph.D., p.

28, 30.) Because of that recognition, Dr. Hughes undertook to go into pertinent details about the various aspects of PGD with the plaintiffs, what procedures PGD involved, and the risk of a PGD misdiagnosis leading to the implantation and development of a CF-affected embryo and the resultant birth of a CF-affected child. (Exhibit E, p. 21-22.)

From Dr. Licciardi and from Dr. Hughes, plaintiffs understood, before they began the IVF/PGD process, that PGD was not 100% accurate, and that there was a risk of PGD misdiagnosis that could lead to the implantation of an CF-affected embryo and the resultant birth of a CF-affected child. (Exhibit B, p. 59-60, 69-72, 107-108, 111, 112, 114, 122 171-173, 175, 177; Exhibit C, p. 29, 34, 65.)[2]

Plaintiffs understood from the information provided by the NYU personnel that the risk of a PGD misdiagnosis was as high as 10% with the success rate "above 90%," but they understood from their previous discussion with Dr. Hughes that he was very positive about the chances of success for the plaintiffs; that his success rate was much higher, 97%-98%; and that his risk rate was much lower and "minimal," 2% to 3%. (Exhibit B, p. 69-72, 111-112, 118-122, 141-142, 213-214; Exhibit C, p. 29, 31, 36-39, 48, 69-70.) Dr. Hughes confirmed that he tells the patients that the risk rate with his testing is less than 2% or 1-2%, compared to a 3-5% risk rate with other PGD testing facilities. (Exhibit E, p. 30-31; Exhibit F, p. 41, 43.)

Plaintiffs decided to go forward with the IVF/PGD process based upon their discussion with Dr. Hughes and his assurance that the success rate would be 97-98%, with a risk rate of 2-

[2] Although there is some dispute as to whether or not plaintiffs, contrary to their indications on consent forms, expressed to the defendants an intention not to undergo the post-conception prenatal tests recommended to them by the defendants and expressly agreed to on the forms, and as to whether Genesis and Dr. Hughes would or could have refused to perform the PGD testing had that intention been known, those disputes are completely immaterial to the resolution of plaintiffs' claims against the NYU defendants on this motion for summary judgment.

3%. (Exhibit B, p. 69-72, 82, 120-122, 141-142, 213-214; Exhibit C, p. 31-32, 36-39, 48, 69-70.) If Mrs. Grossbaum had been told that the success rate was less than 97-98% and the risk higher than 2-3%, but still far better than the inherent 25% risk, she probably would not have had the embryos implanted. (Exhibit B, p. 213-214 ["If I was told that there was a chance, a greater chance than what we had originally understood, I would probably not have implanted the embryo."].) Mr. Grossbaum was guided by and followed his wife's decisions regarding the process. (Exhibit C, p. 36-39.)

Neither plaintiff knew for sure what his or her decision would have been if they had been told that the success rate was not 97-98%, but closer to 90%. (Exhibit B, p. 217-218; Exhibit C, p. 69-70.)

C. DR. HUGHES' PGD REPORT AND THE DECISION TO IMPLANT A "CARRIER AT WORST" EMBRYO

On July 19, 2004, Dr. Hughes faxed his one-page PGD analytical report for use by Dr. Licciardi in determining which of the embryos were genetically suitable for implantation. (Exhibit G, 1-page "Morgenstern-Grossbaum results – 07/19/2004"; Exhibit D, p. 40-41, 43, 45-46; Exhibit F, p. 62, 69-70.) Dr. Hughes expected that Dr. Licciardi would use and rely upon the information conveyed in the one-page report. (Exhibit F, p. 62, 69-70.)[3]

Dr. Hughes' PGD analytical report stated generally that "All controls and media blanks worked as expected. These data are very clear. All media blanks showed no evidence of exogenous DNA contamination." (Exhibit G.)

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[3] Although two other communications from Genesis to NYU exist in the Genesis chart for the plaintiffs, a more formal analytical report and a note, there is no evidence of record that either of those communications were sent to, or received by, NYU. To the contrary, the evidence of record demonstrates that neither of those documents were part of the NYU records. (Exhibit D, p. 44-45, 66; Exhibit H, Deposition of James Grifo, M.D., p. 31-32.)

Dr. Hughes' PGD analytical report mentioned allele drop-out ("ADO") only with respect to the cell from embryo #2, stating in the report's "call", or genetic suitability evaluation, that that cell was "Possibly affected – ADO paternal," and noting, "For sample 2, since only the mutant maternal allele was observed, it is possible that the paternal allele also dropped out of CF 10, and could be affected." (Exhibit G.)

With respect to the cells from embryos 3 and 14, the PGD report's call stated, "No molecular signal." (Exhibit G.)

The PGD report noted that the cells from embryos 8 and 10 were carriers of the maternal CF gene, but that those embryos were genetically suitable for transfer, the call for each of those cells stating, "Carrier maternal - -OK for transfer." (Exhibit G.)

With respect to the cells from the remaining embryos, 4, 7, 13, and 15, Dr. Hughes' PGD report's call was "Carrier at worst." (Exhibit G.) Plaintiff's expert Dr. Charles Strom, a geneticist with Quest Diagnostics, confirmed that the PGD report from Dr. Hughes indicated to Dr. Licciardi that the "Carrier at worst" embryos, including embryo 7 that is at issue in this case, were genetically suitable for implantation, as was embryo 8, the other embryo at issue in this case. (Exhibit I, Deposition of Charles Strom, p. 124.)

Dr. Licciardi understood that Dr. Hughes' PGD report meant that the "Carrier at worst" embryos, including embryo 7, were genetically suitable for implantation, as were the two "Carrier maternal - -OK for transfer" embryos, 8 and 10. (Exhibit D, p. 52-56.) The "Carrier at worst" embryos, including #7, were genetically suitable, because they would not produce a CF-affected child, since only one parental gene was affected and CF required both parental genes to be affected. (Exhibit D., 51-56; Exhibit J, Deposition of Dr. Samuel Pang, p. 69-75.)

The "Carrier at worst" embryos were genetically similar to the plaintiffs, each of whom was a CF "carrier," but neither of whom was affected with CF. (Exhibit B, p. 155, Exhibit H, p. 42; Exhibit J, p. 70.)

In addition to reviewing the PGD report from Dr. Hughes concerning the genetic suitability of the tested embryos, Dr. Licciardi morphologically evaluated the embryos to determine how well the embryos were growing, also on July 19, 2004. (Exhibit D, p. 53-54.) Although embryo 10 was genetically evaluated on Dr. Hughes' report as "Carrier maternal - -OK for transfer," it had not grown well enough in the Embryology Laboratory to be sufficiently viable for implantation; instead, embryos 7 and 8 were selected as candidates for implantation, because they were both genetically suitable – simply carriers -- according to Dr. Hughes' PGD analysis, and they were biologically viable due to the quality of their growth and development. (Exhibit D, p. 51-56.)

Had Dr. Hughes advised Dr. Licciardi that ADO was a concern with embryos 7 and 8, as Dr. Hughes' report had indicated with respect to embryo 2, Dr. Licciardi would have followed Dr. Hughes' ADO concern and discussed that concern with the plaintiffs, because Dr. Hughes was the expert on ADO. (Exhibit D, p. 61, 63-64.)

After reviewing the PGD report from Dr. Hughes, and evaluating the growth of the embryos, Dr. Licciardi discussed the embryo transfer with plaintiffs on July 19, 2004, informing them that the analysis involved both the genetic component from Dr. Hughes' PGD testing and the biological growth component from Dr. Licciardi's evaluation, and that the embryos were carriers at worst and genetically suitable for transfer, according to Dr. Hughes' report. (Exhibit B, 154-156; Exhibit C, p. 58-61; Exhibit D, p. 52-54, 62-63.)

Plaintiffs understood that Dr. Hughes's genetic evaluation indicated that the embryos were CF carriers, but not CF-affected, just like the plaintiffs themselves were CF carriers but not affected, and they consented to the implantation of the embryos 7 and 8, which was done that day. (Exhibit B, 154-156; Exhibit C, p. 58-61.) As Mrs. Grossbaum explained,

> Q According to the records, it was July 19th, which would have been five days after the egg retrieval. Does that sound right?
>
> A Yes.
>
> Q. Tell me what happened.
>
> A They told us to come for the implantation. They said some of the embryos that he tested that were good embryos had cystic fibrosis, and there were some good ones that did not have cystic fibrosis but they were carriers for CF. Did we want to use them? We said yes, and they implanted me with two I believe, two embryos, and they said both of them were carriers for CF.
>
> Q Who had the discussion that you related to us?
>
> A Dr. Licciardi.
>
> Q. Was anyone else present for that discussion other than Dr. Licciardi and you? Was your husband there?
>
> A Yes, I believe he was.
>
> Q. Anybody else present?
>
> A I don't remember.
>
> Q. And when Dr. Licciardi said that there were some good embryos that were CF carriers and asked whether you wanted to go ahead with those, did you have an understanding of what a CF carrier was?
>
> A Yes. I'm a CF carrier. It just means that you carry the gene for CF.
>
> Q. So in other words, it was your understanding that Rosie could be a CF carrier such as you or your husband?
>
> A Correct.
>
> Q And was there any further discussion about that issue, other than what you just relayed to me now? Did you have any questions?
>
> A I don't think I had any specific questions. I knew what it meant to be a CF carrier.
>
> Q. So it was your understanding that according to the testing that Dr. Hughes' lab had done, that the two embryos that they were going to implant in you were both CF carriers?

A Yes, and I said as long as it's just a carrier for CF, then that's fine for me. I don't care if she's a carrier for the gene. Everybody is a carrier for something.

Q. Anything else to that discussion that you haven't told us?

A I mean, I think he just spoke specifically about what he was going to do, what the procedure was, how long it would take, but that's it. That's pretty much it.

Q Was the implantation done that day?

A Yes.

(Exhibit B, p. 154-156.)

The only evidence of record regarding whether the plaintiffs' daughter developed from embryo 7 or embryo 8 is the testimony of both Drs. Grifo and Pang that the medical probability is that it was embryo 8, because it was the more morphologically advanced of the two embryos in growth. (Exhibit H, p. 44-45; Exhibit J, p. 103-104, 114-116, 119-120.) Although plaintiffs' expert, Dr. Strom did not believe that there was a way to answer the question, the question was posed to him with respect to embryos 8 and 10, the latter not having been implanted. (Exhibit I, p. 127-128.) Plaintiff's other liability expert, Dr. Garry Cutting, expressed no opinion on the subject. (Exhibit K, 9/29/09 report of Dr. Garry Cutting; Exhibit L, Deposition of Garry Cutting, M.D.)

D. PLAINTIFFS' LIABILITY EXPERTS REGARDING THE NYU DEFENDANTS

1. Overview

Plaintiffs' liability expert, Dr. Strom, will not be testifying regarding the standard of care of the NYU defendants' Dr. Licciardi. (Exhibit I, p. 5.) As noted above, however, Dr. Strom testified that, according to Dr. Hughes' PGD report, the "Carrier at worst" embryos, including embryo 7, were genetically suitable for implantation, as was embryo 8, one of the two "Carrier maternal - -OK for transfer" embryos. (Exhibit I, p. 124.)

Although there is a dispute between plaintiffs' additional liability expert, Dr. Cutting, and all of the other experts in this case, including Drs. Hughes, Strom, Pang, and Kangpu Xu, as to whether or not embryo 7 or embryo 8 posed the greater risk of genetic misdiagnosis and consequent CF development due to undetected ADO, that dispute is not material -- or contrary -- to the granting of summary judgment in favor of the NYU defendants, because no risk of ADO posed by those embryos was expressed in Dr. Hughes' PGD evaluation report to Dr. Licciardi.

In contrast with Dr. Licciardi, who is board-certified in obstetrics and gynecology as well as in reproductive endocrinology, and who has long maintained an active practice in IVF, Dr. Cutting is primarily a pediatrician and a geneticist who has not practiced as an IVF specialist. (Exhibit M, Curriculum Vitae of Dr. Licciardi; Exhibit N, Curriculum Vitae of Dr. Cutting.) Dr. Cutting does not have the qualifications under New Jersey law to testify against Dr. Licciardi in this case.

Dr. Cutting's approach to this case also stands in contrast to both the geneticist, Dr. Hughes, who recognizes that IVF practitioners do not, and are not expected to, understand genetics any more than he understands IVF, and to the IVF practitioner Dr. Licciardi, who recognizes the distinct areas of knowledge and expertise between himself and a geneticist such as Dr. Hughes. (Exhibit D, p. 61, 63-64; Exhibit E, p. 21-22; Exhibit F, p. 28.) Instead of evaluating Dr. Licciardi's performance as an IVF practitioner, Dr. Cutting criticizes Dr. Licciardi as if Dr. Licciardi were a geneticist, intimately familiar with the specialized techniques, language, and protocols of PGD testing.

Moreover, Dr. Cutting's criticism of Dr. Licciardi also lacks substantial factual support, and the facts of record refute most of that criticism.

2. Dr. Cutting's Qualifications and Opinion on Causation

Dr. Cutting is a board-certified pediatrician and geneticist. (Exhibit N.) He viewed his purpose in this case a **"offering an expert opinion on diagnostic procedures in PGD."** (Exhibit L, p. 253, emphasis added.) In Dr. Cutting's opinion, "[t]he appropriately done [PGD] analysis in 2004 when this was done should have been done with genetic markers." (*Id.*, p. 256.) Dr. Cutting has done only two PGD analyses, both using markers. (*Id.*, p. 117-118, 284, 285.) In Dr. Cutting's view, plaintiffs' daughter became affected with CF, because Genesis and Dr. Hughes did not use markers in their PGD testing, thereby failing to detect an ADO in one of the implanted embryos and misdiagnosing the genetic suitability of the embryo for implantation by Dr. Licciardi. (*Id.*, p. 183, 186, 188-189, 192-193, 199.)

Dr. Cutting counsels, diagnoses, and tests patients on genetics as a geneticist. (Exhibit L, p. 13-23, 28.) Unlike Dr. Licciardi and his IVF colleagues at the NYU defendants, Dr. Cutting has not extracted eggs from patients, and he has not implanted embryos into patients. (*Id.*, p. 13-14.) As Dr. Cutting admitted in his deposition, IVF is not part of his program; "IVF, invitro fertilization is a program of obstetrics and gynecology. It is not under the institute of genetic medicine. **Invitro is not a part of the genetics program here. Just like surgery is not under genetics."** (*Id.*, p. 19, emphasis added.)

Dr. Cutting also admitted that he did not know the grading scale or the basis on which the NYU IVF team determined that one of the embryos in this case was not morphologically viable for implantation or transfer, and he further admitted that he could not talk about how the embryos were tracked in the NYU IVF lab, because **"I'm not an embryologist. Not my area of expertise."** (*Id.*, p. 65-67, emphasis added.) Dr. Cutting recognized that those functions were under the IVF specialty umbrella and areas of expertise for embryologists, "OB/GYN, maternal/fetal medicine, [and] reproductive endocrinology." (*Id.*)

Dr. Cutting additionally admitted that he was not an expert in IVF clinics and laboratories: **"I can't say, I'm not – expert in IVF laboratories.** So, I've – I've already indicated I'm not – will talk about DNA labs but not – I could cite to the areas where I have expertise and be more careful." (Exhibit L, p. 104, emphasis added.)

With respect to the current professional activities listed on his C.V. and those in which he was engaged in 2003-2005, Dr. Cutting explained that 10% of his time is devoted to his role as Director of the Post-Doctoral Training Programs in Medical Genetics, including, until 2008, his role as Director of Genetics Residency Programs; 15% of his time is spent as Director of the DNA Diagnostic Laboratory; his role as Professor of Pediatric Medicine is "primarily [his] research that would take about 70 percent" of his time; and the remaining 5% is devoted to time off. Exhibit L, p. 23-26.)

Dr. Cutting has been involved as an expert in 10 cases, all involving PGD as opposed to IVF; he has given 5 depositions including the two-stage deposition that he gave in this case; but he has never testified at trial. (Exhibit L, p. 35-40.)

3. Dr. Cutting's Criticism of Dr. Licciardi

Dr. Cutting's September 29, 2009 expert report criticized Dr. Licciardi regarding the decision to substitute embryo 7 in place of embryo 10. (Exhibit K., p. 1.) Specifically, Dr. Cutting opined that Dr. Licciardi:

> ….failed to offer a reasonable level of care….in the counseling of the Grossbaums regarding alternatives for embryo transfer after it was discovered that the embryos recommended for transfer by Genesis Genetics were not suitable for transfer. Allele dropout (aka ADO) is a well established source of error in preimplantation genetic diagnosis. From the deposition of Dr. Licciardi, it was apparent that he was not aware of this potential cause for error. Dr. Licciardi indicated during his deposition that he did not understand the results of the genetic testing results transmitted by Genesis Genetics. There is also no documentation of what was said during the counseling session between Dr. Licciardi and the Grossbaum's [sic] regarding the risks of potential sources of error.

> Thus, Dr. Licciardi failed to adequately appraise the Grossbaums of the potential risks of using alternative embryos for transfer.

(Exhibit K, p. 1.)

Contrary to his report, Dr. Cutting acknowledged at his deposition that Dr. Licciardi was, in fact, familiar with the ADO mechanism. (Exhibit L, p. 69-70.) In particular, Dr. Cutting recited what Dr. Licciardi said in his deposition about Dr. Hughes' "call" or evaluation for embryo 2, that it was "Possibly affected due to "ADO paternal," signifying allele drop-out, which meant "[w]hen the test is performed and you don't get your answer, the feeling is you were able to test for one of the alleles." (Exhibit D, p. 50-51; Exhibit L, p. 69-70.)

Dr. Cutting also acknowledged that the "call" section of Dr. Hughes' report provided Dr. Licciardi with Dr. Hughes' genetic evaluation of the embryo; that "carrier at worst" meant that **"the worst this could be is a carrier,"** a meaning which was "obvious"; and that the only mention of ADO and "possibly affected" was with respect to embryo 2. (Exhibit L, p. 70, 76-77, 218-219, emphasis added.)

As an IVF specialist, and admittedly not as a specialist in genetics or in PGD testing, Dr. Licciardi acknowledged at his deposition that he did not know what some of the geneticist abbreviations on Dr. Hughes' report meant, such as "T only," "G," or "G/T." (Exhibit D, p. 49-50.) However, there is nothing in Dr. Cutting's report or in his deposition testimony to establish that the standard of PGD knowledge for an IFV doctor was the same standard of knowledge as for a geneticist, or that the standard of care for an IVF practitioner encompassed the specialized terminology used by genetics specialists.

Contrary to Dr. Cutting's report, but confirmed by his deposition testimony, the record shows that Dr. Licciardi did understand that Dr. Hughes' "call" provided his "assessment of that

embryo that was tested"; the significance of ADO; that ADO was indicated only for embryo 2; that "carrier at worst" meant "that one gene has been determined to be a cystic fibrosis gene and one has not, or it means that there was one gene assessed that is not a carrier and the other gene was unable to be assessed"; **that a "carrier at worst" embryo would be suitable for implantation after discussion with the couple**; and that the only indication of ADO in Dr. Hughes' PGD evaluation was with respect to embryo 2. (Exhibit D, p. 50-52, 64, emphasis added.)

As detailed above, the record also establishes that, while the specifics of the conversation about the implantation of "carrier at worst" embryos were not recorded, both plaintiffs and Dr. Licciardi confirmed in their respective depositions that the conversation took place; that it was based on the evaluation of the embryos' genetic suitability provided by Dr. Hughes' PGD report; and that the decision was made, because the "carrier at worst" embryos were the same as the parents.

Given the testimony of the plaintiffs and Dr. Licciardi about the consultation on and the acceptability to the parents to implant a "carrier at worst" embryo; given the "obvious" meaning of Dr. Hughes' evaluation of an embryo as a "carrier at worst"; and given that Dr. Hughes' PGD analytical report mentioned ADO only with respect to embryo 2, the record conclusively refutes: Dr. Cutting's opinion that Dr. Licciardi "did not understand the results of the genetic testing results transmitted by Genesis Genetics"; Dr. Cutting's criticism that "[t]here is also no documentation of what was said during the counseling session between Dr. Licciardi and the Grossbaum's [sic] regarding the risks of potential sources of error"; and Dr. Cutting's net opinion that "Dr. Licciardi failed to adequately appraise the Grossbaums of the potential risks of using alternative embryos for transfer." (Exhibit K, p. 1.)

Dr. Cutting's criticisms of Dr. Licciardi are not shared by any other expert in this case, including plaintiffs' other liability expert, Dr. Strom, and also notably Dr. Hughes and Genesis' other expert Dr. Xu, whose interests would be expected to naturally tend to exonerate Genesis and Dr. Hughes by shifting responsibility to Dr. Licciardi.

Dr. Cutting's opinion against Dr. Licciardi is also strained. Dr. Cutting can only criticize Dr. Licciardi by treating him as if he were a geneticist, rather than as the distinctly different specialist that he is: an IVF practitioner who was and is board-certified in obstetrics and gynecology and in reproductive endocrinology. Dr. Cutting can only express opinions against Dr. Licciardi by disregarding critical facts, including the "obvious" interpretation of Dr. Hughes' PGD analysis as indicating the genetic suitability of the "maternally affected" embryo #8 as well as the "carrier at best" embryo #7, both of which were genetically equivalent to the plaintiffs, and reasonably so understood by Dr. Licciardi and by the plaintiffs based on Dr. Hughes' evaluation.

On the record of this case, Dr. Cutting's theory against Dr. Licciardi is also inconsistent with Dr. Cutting's primary opinion that the birth of plaintiffs' CF-affected child resulted from a misdiagnosis by Genesis and Dr. Hughes which stemmed from their failure to detect an ADO because they did not use markers in their PGD tests. Dr. Cutting recognized, as did Dr. Licciardi and the plaintiffs, that CF was a recessive disorder that would not occur unless both parental genes were affected, and that the "obvious" message from Dr. Hughes' PGD evaluation report was that both embryos 7 and 8 were CF-carriers but not CF-affected. The only acceptable conclusion is that the birth of plaintiffs' CF-affected child stemmed from the inherent risk of mis-diagnosis in PGD testing (which was always known by the plaintiffs to be a potential result),

rather than from a lack of understanding by Dr. Licciardi of the evaluation actually conveyed by Dr. Hughes' PGD report, that embryos 7 and 8 were genetically suitable for implantation.

III. ARGUMENT

A. THE NYU DEFENDANTS ARE ENTITLED TO SUMMARY JUDGMENT

1. The Standards Applicable To A Motion For Summary Judgment

F.R.Civ.P. 56(b) permits defending parties to move for summary judgment, with or without affidavits F.R.Civ.P. 56(b). F.R.Civ.P. 56(c) provides that summary judgment "shall be rendered forthwith if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." F.R.Civ.P. 56(c).

Summary judgment will be granted and affirmed "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986); *Kreschollek v. S. Stevedoring Co.*, 223 F.3d 202, 204 (3d Cir. 2000).

The moving party "bears the initial responsibility of informing the district court of the basis for its motion, and identifying those portions of 'the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any,' which it believes demonstrate the absence of a genuine issue of material fact." *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986).

"By its very terms, this standard provides that the mere existence of *some* alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment; the requirement is that there be no *genuine* issue of *material* fact. *Anderson*, *supra*,

477 U.S. at 247-248. Additionally, the Court suggested that only disputes over facts that might affect the outcome of the suit under the governing law will properly preclude the entry of summary judgment. Factual disputes that are irrelevant or unnecessary will not be counted. *Id.* at 248.

Once the moving party has made that showing, the non-moving party having the burden of proof at trial "must do more than simply show that there is some metaphysical doubt as to material facts." *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986). The non-moving party must go beyond the pleadings and a mere scintilla of evidence and designate, by affidavits, depositions, answers to interrogatories, and admissions on file, "specific facts showing that there is a genuine issue for trial." *Celotex*, 477 U.S. at 324; *Big Apple BMW, Inc. v. BMW of N. Am., Inc.*, 974 F.2d 1358, 1363 (3d Cir. 1992).

"[T]he mere existence of *some* alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment." *Anderson*, *supra*, 477 U.S. at 247-248 (italics in original). Furthermore, "conclusory, self-serving affidavits are insufficient to withstand a motion for summary judgment. Instead, the affiant must set forth specific facts that reveal a genuine issue of material fact." *Kirleis v. Dickie, McCamey & Chilcote, P.C.*, 560 F.3d 156, 161 (3d Cir. 2009).

"As to materiality, the substantive law will identify which facts are material. Only disputes over facts that might affect the outcome of the suit under the governing law will properly preclude the entry of summary judgment. Factual disputes that are irrelevant or unnecessary will not be counted." *Anderson*, *supra*, 477 U.S. at 248. "The mere existence of a scintilla of evidence in support of the plaintiff's position will be insufficient; there must be evidence on which the jury could reasonably find for the plaintiff. The judge's inquiry, therefore,

unavoidably asks whether reasonable jurors could find by a preponderance of the evidence that the plaintiff is entitled to a verdict – 'whether there is [evidence] upon which a jury can properly proceed to find a verdict for the party producing it, upon whom the *onus* of proof is imposed.'" *Id.* at 252.

Expert opinion that does not consider the facts of record indicating reasonable conduct does not create a material issue of fact. *Carswell v. Borough of Homestead*, 381 F.3d 235, 243 (3d Cir. 2004) ("The plaintiff's expert, Professor McCauley, thought that Snyder should not have pulled his gun but rather should have chosen to tackle or otherwise physically subdue the suspect. The expert's opinion did not refer to the question of mistake and consequently there is no dispute of fact.") (citation omitted). See also, *Brooke Group Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 242 (1993) ("When an expert opinion is not supported by sufficient facts to validate it in the eyes of the law, or when indisputable record facts contradict or otherwise render the opinion unreasonable, it cannot support a jury's verdict.").

In deciding a motion for summary judgment, and without making an impermissible credibility assessment, the court may accept as true the facts provided in deposition testimony when there is no contradictory evidence. *Waskovich v. Morgano*, 2 F.3d 1292, 1296 (3d Cir. 1993) (citation omitted).

If the record, taken as a whole in a light most favorable to the non-moving party, "could not lead a rational trier of fact to find for the non-moving party, there is no genuine issue for trial." *Matsushita*, *supra*, 475 U.S. at 587. If the evidence for the non-moving party is merely colorable, or if it is not significantly probative, summary judgment may be granted. *Anderson*, *supra*, 477 U.S. at 249-250.

In this case, because there is no genuine issue of material fact and because the NYU defendants are entitled to judgment in their favor as a matter of law, summary judgment is appropriate.

2. New Jersey Law Governs This Case

Choice of law in a diversity case is governed by the rules of the forum state. Warriner v. Stanton, 475 F.3d 497, 499-500 (3d Cir. 2007). New Jersey employs the "most significant relationship" test as found in the Restatement (Second) of Conflict of Laws (1971) (the "Restatement") to choice-of-law questions. P.V. v. Camp Jaycee, 197 N.J. 132, 135-136, 962 A.2d 453, 455 (2008) (adopting test); Agostino v. Quest Diagnositcs Inc., 256 F.R.D. 437, 460-461 (D. N.J. 2009) (applying New Jersey's most significant relationship test to plaintiffs' tort and breach of contract claims in class action).

"Under that standard, the analysis in a personal injury case begins with the [Restatement] section 146 presumption that the local law of the state of the injury will apply. Once the presumptively applicable law is identified, that choice is tested against the contacts detailed in section 145 and the general principles outlined in section 6 of the Second Restatement. If another state has a more significant relationship to the parties or issues, the presumption will be overcome. If not, it will govern." P.V., supra, 197 N.J. 132, 135-136, 962 A.2d 453, 455.

The injury in this case occurred in New Jersey where the plaintiffs' daughter was born. Consequently, New Jersey law presumptively applies, unless some other state has a more significant relationship to the parties or the issues. Although defendants Dr. Hughes and Genesis are based in Michigan and the NYU defendants are based in New York, New Jersey has at least four overarching relationships to this case, besides being presumptively the state whose law applies to this case: (1) it is the state where the injury occurred; (2) it is the state where plaintiffs and their child reside; (3) it is the state which has the most direct and most substantial interest in

the economic welfare of plaintiffs and their child; and (4) it has heightened restrictions, applicable as substantive law in its state and federal courts, on the qualifications of experts providing certificates of merit and testimony against medical malpractice defendants such as the NYU defendants.

Accordingly, New Jersey law should govern this case.

3. Plaintiffs Cannot Sustain Their Burden Of Proof Against The NYU Defendants

a. Dr. Cutting's opinion against Dr. Licciardi is inadmissible, because Dr. Cutting is not qualified to testify against Dr. Licciardi, and because Dr. Cutting's opinion is baseless net opinion

(1.) Introduction

Because plaintiffs' liability expert, Dr. Strom, will not be testifying against the NYU defendants regarding their standard of care, plaintiffs' case against the NYU defendants depends entirely on the admissibility of the testimony of plaintiffs' other liability expert, Dr. Cutting. However, plaintiffs' cannot sustain their burden of proof against the NYU defendants, because Dr. Cutting's opinion against Dr. Licciardi is inadmissible, since Dr. Cutting is not qualified to testify against Dr. Licciardi, and since Dr. Cutting's opinion is baseless net opinion.

(2.) Dr. Cutting is not qualified to testify against Dr. Licciardi

The New Jersey Medical Care Access and Responsibility and Patients First Act ("the Act"), L. 2004, c. 17, establishes the minimal qualifications for expert witnesses, and consequently their testimony, in medical malpractice cases litigated in New Jersey courts. The Act has been upheld as constitutional. *N.J. State Bar Ass'n v. State*, 387 N.J. Super. 24, 36-37, 902 A.2d 944, 956 (App. Div.), certif. denied, 188 N.J. 491, 909 A.2d 726 (2006).

Moreover, the Act must be applied in diversity cases brought in the New Jersey federal courts, because the Act does not directly conflict with any dominate federal procedural rule or policy, and because the Act is substantive, outcome-determinative state law that must be applied by federal courts sitting in diversity to avoid forum shopping between the state and the federal courts, and to avoid the inequitable administration of the law by producing a different outcome in a federal court than that mandated in a state proceeding. *Chamberlain v. Giampapa*, 210 F.3d 154, 157, 158-161 (3d Cir. 2000).

The Act specifically prohibits anyone from testifying as an expert (and from executing an affidavit of merit) in a medical malpractice action on the appropriate standard of practice or care unless that person is licensed as a physician or other health care professional in the United States and meets additional specific criteria "generally requiring the challenging expert to be equivalently-qualified to the defendant." *N.J.S.A.* 2A:53A-41; *Ryan v. Renny*, 203 N.J. 37, 52, 999 A.2d 427, 436 (2010).

As noted in the Statement of Facts section of this brief, Dr. Licciardi practices IFV medicine as a board certified specialist in obstetrics and gynecology and in reproductive endocrinology, respectively; a general specialty and a subspecialty recognized by the American Board of Medical Specialties. http://www.abms.org/who_we_help/physicians/specialties.aspx (listing the physician specialties and subspecialties recognized by the American Board of Medical Specialties). Additionally, plaintiffs' claim against the NYU defendants obviously involves Dr. Licciardi's care and treatment as such a physician.

Because Dr. Licciardi is "a specialist or subspecialist recognized by the American Board of Medical Specialties or the American Osteopathic Association and the care or treatment at issue involves that specialty or subspecialty," Dr. Cutting cannot testify against Dr. Licciardi and

the adverse testimony of Dr. Cutting is inadmissible, unless he meets the "equivalently-qualified" criteria provided by the Act, *N.J.S.A.* 2A:53A-41a. Dr. Cutting, however, cannot meet those criteria.

The criteria first require that Dr. Cutting "shall have specialized at the time of the occurrence that is the basis for the action in the same specialty or subspecialty," *N.J.S.A.* 2A:53A-41a. However, Dr. Cutting has never been in the same specialties as Dr. Licciardi. At the time of the birth of the plaintiff's daughter in 2005, and even to the present, Dr. Cutting has admittedly never been board certified either in obstetrics and gynecology or in reproductive endocrinology, and he has never practiced as an IVF specialist. Instead, his board certifications have been in completely different fields and he has practiced only those fields as a pediatrician and as a geneticist.

In addition, with some emphatic redundancy, the criteria mandate that Dr. Cutting either be "a physician credentialed by a hospital to treat patients for the medical condition, or to perform the procedure, that is the basis for the claim or action," or that he be "board certified in the same specialty or subspecialty, recognized by the American Board of Medical Specialties … and during the year immediately preceding the date of the occurrence that is the basis for the claim or action, shall have devoted a majority of his professional time to either: (a) the active clinical practice of the same health care profession in which the defendant is licensed, and, if the defendant is a specialist or subspecialist recognized by the American Board of Medical Specialties…, the active clinical practice of that specialty or subspecialty"; or "(b) the instruction of students in an accredited medical school, other accredited health professional school or accredited residency or clinical research program in the same health care profession in which the defendant is licensed, and, if that party is a specialist or subspecialist recognized by the

American Board of Medical Specialties…, an accredited medical school, health professional school or accredited residency or clinical research program in the same specialty or subspecialty recognized by the American Board of Medical Specialties or the American Osteopathic Association; or (c) both." *N.J.S.A.* 2A:53A-41a(1)-(2).

Dr. Cutting has never been credentialed by a hospital to treat patients and to perform IVF procedures as a specialist in obstetrics and gynecology or in reproductive endocrinology. To the contrary, the hospital for which Dr. Cutting works places its IVF practice in a department that is separate and distinct from Dr. Cutting's genetics-related departments and practice.

Moreover, at no time, including the year immediately preceding the date of the birth of plaintiff's daughter, has Dr. Cutting ever "devoted a majority of his professional time to" the "active clinical practice of" IVF procedures as a specialist in obstetrics and gynecology or in reproductive endocrinology. To the contrary, the majority of Dr. Cutting's professional time has been devoted to his research as a Professor of Pediatric Medicine.

Similarly, at no time, including the year immediately preceding the date of the birth of plaintiff's daughter, has Dr. Cutting ever "devoted a majority of his professional time to" the "instruction of students in an accredited medical school, other accredited health professional school or accredited residency or clinical research program" in IVF, obstetrics and gynecology or reproductive endocrinology. Instead, Dr. Cutting explained that his teaching role was in genetics as Director of Genetics Residency Programs, and that that role was part of the 10% of his time that was and is devoted to his role as Director of the Post-Doctoral Training Programs in Medical Genetics.

Under the Act, Dr. Cutting does not qualify to testify against Dr. Licciardi on the appropriate standard of practice or care for an IVF specialist with specialty training in obstetrics and gynecology and in reproductive endocrinology.

Dr. Cutting counsels, diagnoses, and tests patients on genetics as a geneticist. (Exhibit L, p. 13-23, 28.) Unlike Dr. Licciardi and his IVF colleagues at the NYU defendants, Dr. Cutting has not extracted eggs from patients, and he has not implanted embryos into patients. (*Id.*, p. 13-14.) As Dr. Cutting admitted in his deposition, IVF is not part of his program; "IVF, invitro fertilization is a program of obstetrics and gynecology. It is not under the institute of genetic medicine. Invitro is not a part of the genetics program here. Just like surgery is not under genetics." (*Id.*, p. 19.)

Dr. Cutting also admitted that he did not know the grading scale or the basis on which the NYU IVF team determined that one of the embryos in this case was not morphologically suitable for implantation or transfer, and he further admitted that he could not talk about how the embryos were tracked in the NYU IVF lab, because "I'm not an embryologist. Not my area of expertise." (*Id.*, p. 65-67.) Dr. Cutting recognized that those functions were under the IVF specialty umbrella and areas of expertise for embryologists, "OB/GYN, maternal/fetal medicine, [and] reproductive endocrinology." (*Id.*)

Dr. Cutting additionally admitted that he was not an expert in IVF clinics and laboratories, saying: "I can't say, I'm not – expert in IVF laboratories. So, I've – I've already indicated I'm not – will talk about DNA labs but not – I could cite to the areas where I have expertise and be more careful." (Exhibit L, p. 104.)

Because of his expertise limited to being a pediatrician-geneticist, Dr. Cutting's perspective on this case is likewise limited. Neither in his report nor in his deposition testimony

has Dr. Cutting expressed what specialists in obstetrics and gynecology and in reproductive endocrinology regard as the standard of care applicable to the IVF procedures that Dr. Licciardi conducted as such a specialist. Dr. Cutting has not opined, and cannot opine as such a specialist, simply because he is not such a specialist. Instead, Dr. Cutting can only criticize Dr. Licciardi by treating him as if he were a geneticist, rather than as the distinctly different specialist that he is: an IVF practitioner who was and is board-certified in obstetrics and gynecology and in reproductive endocrinology.

Dr. Cutting cannot qualify under the Act to testify against Dr. Licciardi on the appropriate standard of practice or care for an IVF specialist. Consequently, Dr. Cutting's opinions against Dr. Licciardi cannot be admitted and plaintiffs cannot prove their claim against the NYU defendants. Plaintiffs were certainly free to retain an IVF expert to review this case as against the NYU defendants and serve a liability report, if they could obtain one. However, no such expert report has been served in support of plaintiffs' case. The NYU defendants are, therefore, entitled to the entry of summary judgment in their favor as a matter of law.

(3.) Dr. Cutting's opinion is baseless net opinion

Even if Dr. Cutting were qualified under the Act to testify against Dr. Licciardi, plaintiffs still could not sustain their burden of proof against the NYU defendants on the basis of Dr. Cutting's opinion, because that opinion is baseless net opinion, unsupported by and contrary to the evidence of record.

"Under the Federal Rules of Evidence, it is the role of the trial judge to act as a 'gatekeeper' to ensure that any and all expert testimony or evidence is not only relevant, but also reliable." *Holman Enters. v. Fid. & Guar. Ins. Co.*, 563 F. Supp. 2d 467, 471 (D. N.J. 2008); *Kannankeril v. Terminix Int'l, Inc.*, 128 F.3d 802, 806 (3d Cir. 1997). "The burden is on the

proponent of the testimony to prove its admissibility by a preponderance of proof." Holman (citation omitted).

To be admissible, expert testimony must be both relevant and reliable. *Daubert v. Merrell Dow Pharms.*, 509 U.S. 579, 589 (1993); *Kumho Tire Co.*, 526 U.S. 137, 141 (1999). Federal Rule of Evidence 702 sets out the standard for the admissibility of expert testimony, providing in pertinent part:

> if scientific, technical, or other specialized knowledge will assist the trier of fact . . . a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto . . . if (1) the testimony is based on sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Fed. R. Evid. 702.

Federal Rule of Evidence 702 "has three major requirements: (1) the proffered witness must be an expert, i.e., must be qualified; (2) the expert must testify about matters requiring scientific, technical or specialized knowledge; and (3) the expert's testimony must assist the trier of fact." *Holman*, *supra*, 563 F. Supp. 2d at 471 (footnote and citation omitted). The third requirement is also known as the "fit" requirement. *Id.* "The net opinion rule is merely a restatement of the well-settled principle that an expert's bare conclusions are not admissible under [the fit requirement of] Rule 702 of the Federal Rules of Evidence." *Id.*, n. 12.

"The opinions of experts must be based either upon facts within their own knowledge which they detail to the jury or upon hypothetical questions embracing facts supported by the evidence upon which the expert opinion is sought. Where the opinion is so completely lacking in proper foundation as to be worthless it is not admissible. Expert opinion is valueless unless it is rested upon the facts which are admitted or are proved." *Stanley Co. of America v. Hercules Powder Co.*, 16 N.J. 295, 305, 108 A.2d 616, 621 (1954). "The 'net opinion' rule renders

inadmissible any opinion consisting of bare conclusions that are unsupported by factual evidence. An expert must 'give the why and wherefore' of his or her opinion, rather than a mere conclusion." *Froom v. Perel*, 377 N.J. Super. 298, 317, 872 A.2d 1067, 1078 (App. Div. 2005). See also *Buckelew v. Grossbard*, 87 N.J. 512, 524, 435 A.2d 1150, 1156 (1981).

Similarly, federal courts recognize that "[a]n expert opinion is not admissible if the court concludes that an opinion based upon particular facts cannot be grounded upon those facts," and that "if an expert opinion is based on speculation or conjecture, it may be stricken." Holman, supra, 563 F. Supp. 2d at 471 (citations omitted). Nothing "requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert." *Kumho Tire*, *supra*, 526 U.S. at 157; *Holman*, 563 F. Supp. 2d at 471-472 (citations omitted).

Contrary to his report, Dr. Cutting acknowledged at his deposition that Dr. Licciardi was, in fact, familiar with the ADO mechanism. (Exhibit L, p. 69-70.) In particular, Dr. Cutting recited what Dr. Licciardi said in his deposition about Dr. Hughes' "call" or evaluation for embryo 2, that it was "Possibly affected due to "ADO paternal," signifying allele drop-out, which meant "[w]hen the test is performed and you don't get your answer, the feeling is you were able to test for one of the alleles." (Exhibit D, p. 50-51; Exhibit L, p. 69-70.)

Dr. Cutting also acknowledged that the "call" section of Dr. Hughes' report provided Dr. Licciardi with Dr. Hughes' genetic evaluation of the embryo; that "carrier at worst" meant that "the worst this could be is a carrier," a meaning which was "obvious"; and that the only mention of ADO and "possibly affected" was with respect to embryo 2. (Exhibit L, p. 70, 76-77, 218-219.)

As an IVF specialist, and admittedly not as a specialist in genetics or in PGD testing, Dr. Licciardi acknowledged at his deposition that he did not know what some of the geneticist

abbreviations on Dr. Hughes' report meant, such as "T only," "G," or "G/T." (Exhibit D, p. 49-50.) However, there is nothing in Dr. Cutting's report or in his deposition testimony to establish that the standard of knowledge of PGD for an IFV doctor was the same standard of knowledge as for a geneticist, or that the standard of care for an IVF practitioner encompassed the specialized terminology used by genetics specialists.

Contrary to Dr. Cutting's report, but confirmed by his deposition testimony, the record shows that Dr. Licciardi did understand that Dr. Hughes' "call" provided his "assessment of that embryo that was tested"; the significance of ADO; that ADO was indicated only for embryo 2; that "carrier at worst" meant "that one gene has been determined to be a cystic fibrosis gene and one has not, or it means that there was one gene assessed that is not a carrier and the other gene was unable to be assessed"; that a "carrier at worst" embryo would be suitable for implantation after discussion with the couple; and that the only indication of ADO in Dr. Hughes' PGD evaluation was with respect to embryo 2. (Exhibit D, p. 50-52, 64.)

As detailed above, the record also establishes that, while the specifics of the conversation about the implantation of "carrier at worst" embryos were not recorded, both plaintiffs and Dr. Licciardi confirmed in their respective depositions that the conversation took place; that it was based on the evaluation of the embryos' genetic suitability provided by Dr. Hughes' PGD report; and that the decision was made, because the "carrier at worst" embryos were the same as the parents.

Given the testimony of the plaintiffs and Dr. Licciardi about the consultation on and the decision by the parents to implant a "carrier at worst" embryo; given the "obvious" meaning of Dr. Hughes' evaluation of an embryo as a "carrier at worst"; and given that Dr. Hughes' PGD analytical report mentioned ADO only with respect to embryo 2, the record conclusively refutes:

Dr. Cutting's opinion that Dr. Licciardi "did not understand the results of the genetic testing results transmitted by Genesis Genetics"; Dr. Cutting's criticism that "[t]here is also no documentation of what was said during the counseling session between Dr. Licciardi and the Grossbaum's [sic] regarding the risks of potential sources of error"; and Dr. Cutting's net opinion that "Dr. Licciardi failed to adequately appraise the Grossbaums of the potential risks of using alternative embryos for transfer." (Exhibit K, p. 1.)

Dr. Cutting's opinions against Dr. Licciardi are patently inadmissible as unfounded net opinions that do not "fit" with, and actually run counter to, the facts of record in this case.

Dr. Cutting can only express opinions against Dr. Licciardi by disregarding critical facts, including the "obvious" interpretation of Dr. Hughes' PGD analysis as indicating the genetic suitability of the "maternally affected" embryo #8 as well as the "carrier at best" embryo #7, both of which were genetically equivalent to the plaintiffs, and reasonably so understood by Dr. Licciardi and by the plaintiffs based on Dr. Hughes' evaluation.

On the record of this case, Dr. Cutting's theory against Dr. Licciardi is also inconsistent with Dr. Cutting's primary opinion that the birth of plaintiffs' CF-affected child resulted from a misdiagnosis by Genesis and Dr. Hughes which stemmed from their failure to detect an ADO because they did not use markers in their PGD tests. Dr. Cutting recognized, as did Dr. Licciardi and the plaintiffs, that CF was a recessive disorder that would not occur unless both parental genes were affected, and that the "obvious" message from Dr. Hughes' PGD evaluation report was that both embryos 7 and 8 were CF-carriers, but not CF-affected. The only acceptable conclusion is that the birth of plaintiffs' CF-affected child stemmed from the inherent risk of mis-diagnosis in PGD testing (which was always known by the plaintiffs to be a potential result),

rather than from a lack of understanding by Dr. Licciardi of the evaluation actually conveyed by Dr. Hughes' PGD report, that embryos 7 and 8 were genetically suitable for implantation.

Dr. Cutting's opinions against Dr. Licciardi cannot be admitted and plaintiffs cannot prove their claim against the NYU defendants. Summary judgment should, therefore, be entered in favor of the NYU defendants as a matter of law.

b. The record establishes that Dr. Licciardi was not negligent and did not cause plaintiffs' harm

(1.) The record establishes that Dr. Licciardi was not negligent

The Genesis PGD report was drafted and sent for Dr. Licciardi's immediate use in determining which of the embryos was genetically suitable for implantation, and Dr. Hughes admitted that there was nothing wrong with Dr. Licciardi's use of the report for that purpose.

Given Dr. Cutting's admission that Dr. Hughes' PGD evaluation for embryo 7 as "Carrier at worst" obviously meant the embryo was not affected but merely a CF-carrier at most; given that the only mention of ADO on Dr. Hughes' PGD report referred just to embryo 2; and given that Dr. Cutting raised no criticism against the implantation of embryo 8, even though he recognized that it, too, was a CF carrier; and given that no expert contradicts Dr. Licciardi's evaluations of embryos 7, 8 and 10 as to their respective developmental viability for implantation, no reasonable person could acceptably find that Dr. Licciardi was negligent when he evaluated embryo 10 as developmentally unfit for implantation and recommended the implantation of embryos 7 and 8, because they were developmentally viable and were genetically evaluated by Dr. Hughes as "carriers" that were not CF-affected.

Moreover, Dr. Cutting's admissible testimony as a geneticist against Dr. Hughes and Genesis rules out negligence on the part of Dr. Licciardi by holding that the cause of the birth of plaintiffs' daughter with CF was the inability of Genesis and Dr. Hughes to diagnose – and

therefore to disclose to Dr. Licciardi and ultimately the plaintiffs -- that one or both of the implanted embryos was or could be CF-affected. As a board-certified pediatrician and geneticist (Exhibit N), Dr. Cutting viewed his purpose in this case a "offering an expert opinion on diagnostic procedures in PGD." (Exhibit L, p. 253.) In Dr. Cutting's opinion, "[t]he appropriately done [PGD] analysis in 2004 when this was done should have been done with genetic markers." (*Id.*, p. 256.) According to Dr. Cutting, plaintiffs' daughter became affected with CF because Genesis and Dr. Hughes did not use markers in their PGD testing, thereby failing to detect an ADO in one of the implanted embryos and misdiagnosing the genetic suitability of the embryo for implantation by Dr. Licciardi. (*Id.*, p. 183, 186, 188-189, 192-193, 199.)

The lack of a legitimate basis for a reasonable jury to find that Dr. Licciardi was negligent in recommending embryo 7 for implantation means that the NYU defendants are entitled as a matter of law to the entry of summary judgment in their favor.

Similarly, because the record establishes that Dr. Licciardi and his staff informed plaintiffs of the IVF risks known to them that a reasonable patient would have wanted to know in order to decide whether or not to proceed with the IVF/PGD/implantation process, and because no qualified expert opines to the contrary, the NYU defendants cannot be held liable, under New Jersey law, for allegedly failing to provide information to the plaintiffs. Consequently, they are entitled to summary judgment on plaintiffs' claims as a matter of law.

(2.) The record establishes that Dr. Licciardi did not cause plaintiffs' harm

The same result obtains from a consideration of the causation aspects of plaintiffs' claim against the NYU defendants.

As delineated previously in this brief, the record in this case establishes that NYU generally informed plaintiffs that the PGD process was not error-free and that there was a substantial risk, ranging as high as 10%, that the process could erroneously fail to detect a CF-affected embryo cell, and result in the implantation of a CF-affected embryo. Despite that information, plaintiffs decided to go forward with the PGD/IVF/implantation. They have acknowledged that they based their decision to proceed on the more positive and specific risk discussion and assessment provided to them by the PGD expert, Dr. Hughes. Similarly, based on Dr. Hughes' report that embryo 7 was a "carrier at worst," which obviously meant that it was deemed by PGD testing not to be a CF-affected embryo, Dr. Licciardi suggested, and plaintiffs acceded, to the implantation of that embryo, along with the "carrier maternal" embryo 8.

No expert faults Dr. Licciardi's determination that embryo 10 was not developmentally viable for implantation. No expert faults Dr. Licciardi for following Dr. Hughes' PGD analysis and implanting embryo 8, even though that embryo was also noted to be a CF carrier. Additionally, even Dr. Cutting admits that the import of Dr. Hughes' call as to embryo 7 was "obvious", that it was not CF-affected, and at worst, the same as the plaintiffs themselves (carrier). There is therefore no basis on this record for a jury to reasonably find that Dr. Licciardi was negligent in suggesting the implantation of embryo 7.

Moreover, the plaintiffs' testimony establishes two additional conclusive facts that preclude holding the NYU defendants liable in this case:

First, the plaintiffs' own testimony makes it clear and indisputable that they based their decision on the risk assessment provided by Dr. Hughes, and not on the higher risk assessment provided by NYU, and that they would not have proceeded with the PGD/IVF/implantation process if Dr. Hughes' assessment had been higher. (Exhibit B, p. 213-214; Exhibit C, p. 36-39.)

Second, plaintiffs' testimony also establishes decisively that they were informed, again based on Dr. Hughes' PGD assessment, that the embryos to be implanted were assessed by PGD testing to be CF carriers, and with that information fully understood, they consented to the implantation of those embryos.

Although plaintiffs' complaint does not spell out whether their medical malpractice claim against the NYU defendants involves both "wrongful birth" and "informed consent," the New Jersey Supreme Court has drawn a distinction between the causation element of a "wrongful birth" claim and the causation element of an "informed consent" claim. "Legal or proximate cause is clearly an essential element of a wrongful birth cause of action. Medical causation, however, is not." *Canesi v. Wilson*, 158 N.J. 490, 514, 730 A.2d 805, 817 (N.J. 1999) But, medical causation is an essential element of an informed consent claim. As the Court explained:

> In sum, the informed consent and wrongful birth causes of action are similar in that both require the physician to disclose those medically accepted risks that a reasonably prudent patient in the plaintiff's position would deem material to her decision. What is or is not a medically accepted risk is informed by what the physician knows or ought to know of the patient's history and condition. These causes of action, however, have important differences. They encompass different compensable harms and measures of damages. In both causes of action, the plaintiff must prove not only that a reasonably prudent patient in her position, if apprised of all material risks, would have elected a different course of treatment or care. In an informed consent case, the plaintiff must additionally meet a two-pronged test of proximate causation: she must prove that the undisclosed risk actually materialized and that it was medically caused by the treatment. In a wrongful birth case, on the other hand, a plaintiff need not prove that the doctor's negligence was the medical cause of her child's birth defect. Rather, the test of proximate causation is satisfied by showing that an undisclosed fetal risk was material to a woman in her position; the risk materialized, was reasonably foreseeable and not remote in relation to the doctor's negligence; and, had plaintiff known of that risk, she would have terminated her pregnancy. The emotional distress and economic loss resulting from this lost opportunity to decide for herself whether or not to terminate the pregnancy constitute plaintiff's damages.

Canesi, 158 N.J. at 506, 730 A.2d at 813.

In the context of this case, plaintiffs cannot prove the medical causation element of their "informed consent" claim against the NYU defendants, because they cannot establish that their daughter developed from embryo 7.[4] Plaintiffs' expert Dr. Cutting offered no opinion on that point, and their expert Dr. Strom could not answer the question as posed. The only testimony of record on this issue is that of the NYU defendants', Dr. Grifo, and their expert, Dr. Pang, to the effect that plaintiffs' daughter developed from embryo 8, because that embryo's growth and development had progressed better than the growth of embryo 7. (Exhibit H, p. 44-45; Exhibit J, p. 103-104, 114-116, 119-120.)

Furthermore, plaintiffs also cannot prove the proximate causation required to sustain their wrongful birth claim against the NYU defendants. On that precise point, the record establishes with preclusive certainty that plaintiffs predicated their decision to proceed with the IVF/PGD/implantation process solely on the risk assessment that Dr. Hughes gave to them, and not on the higher risk assessment that NYU gave them, and that they would not have proceeded with the IVF/PGD/implantation process if Dr. Hughes' risk assessment had been higher than what he conveyed to them.

Additionally, plaintiffs' admitted inability to say what course they would have followed if Dr. Hughes' risk assessment had dovetailed with the 10% risk assessment that NYU provided precludes the jury from finding that the 10% risk assessment proximately caused Mrs. Grossbaum to proceed with the IVF/PGD/implantation process and experience the allegedly ensuing damages. *Provenzano v. Integrated Genetics*, 66 F. Supp. 2d 588 (D.N.J. 1999)

[4] Plaintiffs do not fault the NYU defendants for the implantation of embryo 8, and, except for the inadmissible opinion of their unqualified expert Dr. Cutting, plaintiffs offer no expert opinion that Dr. Licciardi knew or should have known that Dr. Hughes and Genesis had misdiagnosed either embryo 7 or embryo 8 and thereby failed to detect that whichever embryo developed into plaintiffs' daughter was actually CF-affected, rather than only a CF carrier at worst or only a carrier of the maternal CF gene.

("because Mrs. Provenzano's inability to say that she would have terminated the pregnancy precludes a jury from finding that the alleged negligence proximately caused the extraordinary medical expenses.").

Since the record precludes a finding that the NYU defendants caused the plaintiffs' harm, the NYU defendants are entitled to summary judgment in their favor as a matter of law.

B. THE COURT'S GRANT OF SUMMARY JUDGMENT SHOULD BE MADE FINAL

When the case presents more than one claim for relief or involves more than one party, F.R.Civ.P. 54(b) permits the Court to enter a final judgment as to fewer than all claims or parties by expressly determining that there is no just reason for delay. In this case, the Court's grant of summary judgment in favor of the NYU defendants should be made final, because there is no just reason to delay the finality of that judgment pending the resolution of plaintiffs' claims against Genesis, since those claims are distinct and can be separated from the claims against the NYU defendants, and since the NYU defendants are presently entitled to the entry of judgment in their favor.

The Supreme Court has "outlined the steps to be followed in making determinations under Rule 54 (b)." *Curtiss-Wright Corp. v. General Elec. Co.*, 446 U.S. 1, 7 (1980) (existence of nonfrivolous counterclaims does not preclude entry of 54(b) judgment) (citation omitted). "A district court must first determine that it is dealing with a 'final judgment.' It must be a 'judgment' in the sense that it is a decision upon a cognizable claim for relief, and it must be 'final' in the sense that it is "an ultimate disposition of an individual claim entered in the course of a multiple claims action." *Id.*

Plaintiffs' claim against the NYU defendants is unquestionably a cognizable claim for relief; it constitutes a separate count in plaintiffs' complaint. Likewise, summary judgment for

the NYU defendants on that claim is unquestionably an ultimate disposition of that claim, since nothing would remain to be litigated on that claim, and the plaintiffs (as well as the co-defendants) would be precluded from recovering against the NYU defendants.

"[I]n deciding whether there are no just reasons to delay the appeal of individual final judgments in a setting such as this, a district court must take into account judicial administrative interests as well as the equities involved. Consideration of the former is necessary to assure that application of the Rule effectively 'preserves the historic federal policy against piecemeal appeals.' It was therefore proper for the District Judge here to consider such factors as whether the claims under review were separable from the others remaining to be adjudicated and whether the nature of the claims already determined was such that no appellate court would have to decide the same issues more than once even if there were subsequent appeals." *Curtiss-Wright*, 446 U.S. at 8 (citation and footnote omitted).

Although the satisfaction of both of those administrative interests is not necessary, an entry of a final judgment in favor of the NYU defendants would satisfy both of those considerations, because that grant of summary judgment would involve the resolution of a claim separate from the plaintiffs' claim against Genesis and Dr. Hughes, and the Court of Appeals would not have to decide the same issues leading to a final judgment for the NYU defendants more than once in a subsequent appeal on the plaintiffs' claim against Genesis and Dr. Hughes.

Finally, the equities warrant the finality of the summary judgment granted to the NYU defendants. There is no reason to make them wait for the resolution of the separate claim against Genesis and Dr. Hughes. "The function of the district court under the Rule is to act as a 'dispatcher.' It is left to the sound judicial discretion of the district court to determine the 'appropriate time' when each final decision in a multiple claims action is ready for appeal."

Curtiss-Wright, 446 U.S. at 8 (citation omitted). The time for an appeal, if any, on the summary judgment to which the NYU defendants are entitled as a matter of law should be now, not later.

Accordingly, the NYU defendants respectfully ask this Court to expressly make its summary judgment in their favor final pursuant to F.R.Civ.P. 54(b).

IV. CONCLUSION

Accordingly, the NYU defendants respectfully ask this Court to enter an Order granting summary judgment in their favor pursuant to F.R.Civ.P. 56 and making that judgment final pursuant to F.R.Civ.P. 54(b).

Respectfully submitted,

MARSHALL, DENNEHEY, WARNER,
COLEMAN & GOGGIN

By: *R. Scott Eichhorn, Esquire*
425 EAGLE ROCK AVENUE, SUITE 302
ROSELAND, NJ 07068
DIRECT DIAL TELEPHONE: (973) 618-4154
FAX: (973) 618-0685
EMAIL: rseichhorn@mdwcg.com
ATTORNEY FOR DEFENDANTS,
NEW YORK UNIVERSITY SCHOOL OF MEDICINE
and
NEW YORK UNIVERSITY HOSPITALS CENTER

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